Prenylflavanoids as a biomarker of beer consumption

Submission date	Recruitment status No longer recruiting	Prospectively registered		
24/04/2013		[_] Protocol		
Registration date 16/05/2013	Overall study status Completed	[] Statistical analysis plan		
		[X] Results		
Last Edited 23/05/2014	Condition category Nutritional, Metabolic, Endocrine	Individual participant data		

Plain English summary of protocol

Background and study aims

Prenylflavanoids (a group of plant hormones) are mainly found in hops, and therefore, in beer. Thus, the intake of beer might be assessed through its quantity present in the urine. The aim of this study is to assess the usefulness of urinary prenylflavanoids as a biomarker of beer consumption.

Who can participate?

Healthy adults, in the age range 18-35 years, non-smokers, without previous history of heart, liver or kidney disease, disorders with body balance, any other long-lasting diseases, high blood pressure or Dyslipidemia (abnormal cholesterol/fat level in the blood), alcoholism or other toxic abuse.

What does the study involve?

The volunteers were given different doses of beer at dinner in a random order. Male volunteers consumed 330, 660 and 990 ml of beer, and female volunteers consumed 330, 495 and 660 ml of beer. Before each dose, volunteers followed a 4-day wash-out period in which they were requested to avoid consuming any type of hop-based products and beer. Urine sample was collected before each dose.

What are the possible benefits and risks of participating? There are no risks as long as the exclusion criteria are followed. The study was conducted according to the Declaration of Helsinki of the World Medical Association. The study was explained to subjects through verbal and written instructions, and written informed consent was obtained before participation.

Where is the study run from?

This study involved the Department of Nutrition and Food Science of the University of Barcelona (Barcelona, Spain) and the Department of Internal Medicine, Hospital Clinic, Institut d Investigació Biomèdica August Pi i Sunyer (IDIBAPS), University of Barcelona (Barcelona,Spain).

When is the study starting and how long is it expected to run for? This study was conducted between March 2011 and October 2011. Who is funding the study? This study was supported by the European Foundation for Alcohol Research (ERAB) (Belgium).

Who is the main contact? Dr. Rosa Lamuela-Raventós, Nutrition and Food Science Department, School of Pharmacy, University of Barcelona, Av. Joan XXIII, s/n 08028 Barcelona, Spain. E-mail: lamuela@ub.edu Fax+34-934035931; Tel: +34-934034843

Contact information

Type(s) Scientific

Contact name Prof Rosa Maria Lamuela Raventos

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title Urinary isoxanthohumol excretion as a biomarker of beer consumption

Study objectives

Hops and beer are a unique source of xanthohumol, isoxanthohumol and 8-prenylnringenin. Therefore, prenylflavanoids, such as isoxanthohumol and their metabolites may be a potent biomarker of beer consumption, thus the intake of beer can be assessed by quantifying isoxanthohumol in urine.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of University of Barcelona (Institutional Review Board IRB00003099), 04/07 /2011

Study design Dose-response randomised cross-over clinical trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Not specified

Study type(s) Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Beer consumption

Interventions

Male volunteers: Intervention 1: Administration of 330 mL beer (14.5 g ethanol) Intervention 2: Administration of 660 mL beer (29 g ethanol) Intervention 3: Administration of 990 mL beer (43.5 g ethanol)

Female volunteers: Intervention 1: Administration of 330 mL beer (14.5 g ethanol) Intervention 2: Administration of 495 mL beer (21.7 g ethanol) Intervention 3: Administration of 660 mL beer (29 g ethanol)

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

Concentrations of urinary prenylflavanoids will be determined by liquid chromatography coupled to tandem mass spectrometry (LCMS/MS). These determinations will be carried out in first morning urine samples collected the day before the first intervention and in the subsequent mornings following each intervention. Creatinine adjustment will be used to normalize analyte concentrations in these urine samples.

Secondary outcome measures No secondary outcome measures

Overall study start date 31/03/2011

Completion date 28/10/2011

Eligibility

Key inclusion criteria Young healthy volunteers of age 28±3 years, body mass index 22.69±2.69 kg/m2

Participant type(s) Healthy volunteer

Age group Adult

AUUII

Sex Both

Target number of participants 41 (20 men and 21 women)

Key exclusion criteria

 Previous history of cardiovascular disease (ischemic heart disease criteria - angina, recent or old myocardial infarction, cerebral vascular accident or peripheral vascular disease)
 Homeostatic disorders
 Any several chronic diseases
 Hypertension or dyslipidemia
 Smoking subjects
 Alcoholism
 Other toxic abuse

Date of first enrolment

31/03/2011

Date of final enrolment 28/10/2011

Locations

Countries of recruitment Spain **Study participating centre Av. Joan XXII s/n** Barcelona Spain 08028

Sponsor information

Organisation

Center for Biomedical Research in Pathophysiology of Obesity & Nutrition (Ciber Fisiopatología de la Obesidad Nutrición)(Spain)

Sponsor details CENTRO HOSPITALARIO UNIVERSITARIO SANTIAGO DE COMPOSTELA EDIFICIO D 1ª PLANTA CHOUPANA S/N CIF: G 84 884 428 SANTIAGO DE COMPOSTELA Spain 15706 Iamuela@ub.edu

Sponsor type Research organisation

ROR https://ror.org/02s65tk16

Funder(s)

Funder type Research organisation

Funder Name Center for Biomedical Research in Pathophysiology of Obesity and Nutrition (CIBERobn) (Spain)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2014		Yes	No